

**REMARKS/ARGUMENTS****Summary of Status of Amendments**

Initially, Applicants note with appreciation that the Examiner has allowed claims 14, 21-24, and 38.

In the present amendment, claims 25-28 and 38 are amended, and claims 1-13, 15-20, 37, and 39 are canceled, with claims 1-4, 8-9, 14-15, and 39 being independent claims. Claims 1-39 will remain pending with claims 15, 25-36, and 39 under consideration.

Applicants note that claims 25-28 have been amended as suggested by the Examiner to further clarify Applicants' invention in regard to "treated product of the culture." Applicants note that support for the amendment may be found throughout Applicants' originally filed disclosure. Claim 38 has been amended to further clarify Applicants' invention in regard to the recited protein. No new matter has been added.

Applicants note that the abstract has been amended to remove the term "said."

Reconsideration and withdrawal of the rejections and allowance of the application are respectfully requested.

**Claim of Priority**

Applicants express appreciation for the acknowledgement of the claim of priority to JP 11/21707 filed January 29, 1999, as well as receipt of the certified copy of the document.

**Restriction Requirement**

In response to the Examiner's request to cancel claims 1-13 and 16-20, drawn to a non-elected invention, Applicants have canceled claims 1-13 and 16-20 in order to advance prosecution of the present application. However, Applicants reserve the right to file the canceled claims in a continuation application, continuation-in-part application, or divisional application.

**Information Disclosure Statement**

Applicants express appreciation for the consideration of the Information Disclosure Statement, filed January 14, 2005, by including an initialed copy of the Form PTO-1449 submitted therewith.

**Response to Objections to Specification and Claim**

The Office Action objects to the specification because the abstract includes the term "said." In response, Applicants have amended the abstract to remove the term "said."

Claim 37 is objected by the Examiner because it is asserted that even though the claim appears to be allowable, the claim is dependent on a rejected base claim 25. In response, Applicants have canceled claim 37.

**Rejections under 35 U.S.C. § 112****Rejections for Indefiniteness**

Claims 15 and 25-36 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In response, and without acquiescence, Applicants have canceled claim 15 in order to advance prosecution of the present application.

Claims 25-28 remain indefinite because of the recitation "treated product of the culture" is not defined in the specification. It is suggested by the Office Action that the claims be amended to include the limitations of claim 37 in regard to "treated product of the culture," and claim 37 canceled.

In response, Applicants have amended claims 25-28 as suggested by the Examiner.

Therefore, the rejection of claims 15 and 25-36 under 35 U.S.C. §112, second paragraph should be withdrawn.

**Rejections for Written Description**

Claims 15 and 25-36 remain rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement because the claims contain subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was

filed, had possession of the claimed invention. Claim 15 is rejected because the Office Action asserts that this is a new matter rejection in view of the amendment. The Office Action asserts that claims 25-36 remain rejected for reasons discussed in the Office Action mailed July 14, 2005, relating to the term "treated product of the culture." The Office Action asserts that since the claims have been interpreted as directed to a process for producing the recited compounds with any fraction of the culture, including one which lacks the enzyme, the rejection is maintained for reasons of record. The Office Action asserts that the rejection may be overcome by amending claims 25-28 to include the limitations of claim 37 in regard to what is encompassed by the term "treated product of the culture," and cancellation of claim 37.

In response, Applicants note that claims 15 and 37 contain subject matter that is sufficiently described in the specification, however, in order to advance prosecution of the present application, claims 15 and 37 have been canceled as suggested.

In regard to claims 25-36, Applicants note that one of ordinary skill in the art would understand from reading the guidance set forth in the instant specification, that the "treated products of the culture" include dried cells, lyophilized cells, cells treated with surfactants, cells treated with enzymes, cells treated with ultrasonication, cells treated with mechanical milling, cells treated with solvents, protein fractions of the cells, or immobilized product of cells. However, in order to advance prosecution of the present application, Applicants have amended claims 25-28 as suggested to further clarify Applicants' invention.

Therefore, the rejection of claims 15 and 25-36 under 35 U.S.C. §112, first paragraph should be withdrawn.

### **Rejections for Enablement**

Claims 25-36 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement for reasons provided in the Office Action dated July 14, 2004, and because it is asserted that the specification, while being enabling for a process for producing the specific compounds recited with (a) polypeptide of SEQ ID NO: 1, or (b) a fraction of a culture containing the polypeptide of SEQ ID NO: 1, does not reasonably provide enablement for a process for producing the specific compounds recited with a fraction of a culture which does not comprise the polypeptide of SEQ ID NO: 1. The Office Action asserts that the rejection may be overcome by amending claims 25-28 as described above to recite the limitations of claim 37 in regard to what is encompassed by the term "treated product of the culture," and cancellation of claim 37.

In response, and as discussed above, one of ordinary skill in the art would know that the specification enables the invention of claims 25-36. However, for the purpose of advancing prosecution of the present application, claim 37 is canceled and claims 25-28 has been amended to include the recitation "wherein the treated product of the culture of the transformant is a treated product selected from cultured cells, dried cells, freeze-dried cells, cells treated with a surfactant, cells treated with an enzyme, cells

treated by ultrasonication, cells treated by mechanical milling, cells treated by solvent, a protein fraction of a cell, and immobilized cells."

Therefore, the rejection of claims 25-36 under 35 U.S.C. §112, first paragraph should be withdrawn.

**Rejection Under 35 U.S.C. § 102(b)**

Claim 15 is rejected under 35 U.S.C. § 102(b) as being anticipated by Rivolta et al. (Microbiology 144: 877-884, 1998) for reasons discussed in the Office Action dated July 14, 2005.

In response, and without acquiescence, Applicants have canceled claim 15 in order to advance prosecution of the present application. Therefore, the rejection of claim 15 under 35 U.S.C. § 102(b) is moot.

**Rejection Under 35 U.S.C. § 103(a)**

Claim 39 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Rivolta et al. for reasons discussed in the Office Action dated July 14, 2005.

In response, and without acquiescence, Applicants have canceled claim 39 in order to advance prosecution of the present application. Therefore, the rejection of claim 39 under 35 U.S.C. 103(a) is moot.

**CONCLUSION**

For the reasons advanced above, Applicants respectfully submit that all pending claims patentably define Applicants' invention. Allowance of the application with an early mailing date of the Notices of Allowance and Allowability is therefore respectfully requested.

Respectfully submitted,  
Hirofumi ENDO et al.

A handwritten signature in black ink, appearing to read "Bruce H. Bernstein", written over a horizontal line.

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